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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/664,331 | 09/16/2003 | Laurent Humeau | 397272000401 | 4194 |
| 25225 | 7590 | 11/29/2005 | EXAMINER. | |
| MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040 | | | PARKIN, JEFFREY S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1648 | |

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|--|--|
| Office Action Summary | Application No. 10/664,331 | Applicant(s) HUMEAU, L, ET AL. | |
| | Examiner Jeffrey S. Parkin, Ph.D. | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 01 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30, 33-64, 66-71 and 83-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30, 33-64, 66-71, 83-93 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Restriction Requirement

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 19 September, 2005. Claims 1-30, 33-64, 66-71, and 83-93 are pending in the instant application. In response to applicants' comments, the following supplemental restriction requirement is being set forth.

35 U.S.C. § 121

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- a. Group I, claim(s) 1-30, 33-64, 66-71, 83, 84, and 88-93, drawn to ***in vitro/ex vivo*** methods of transducing primary cells of the hematopoietic system using a lentiviral vector and cell surface binding molecule, classified in class 435, subclass 456.
- b. Group II, claim(s) 85, drawn to a method for the introduction of transduced cells into a living subject, classified in class 435, subclass 325.
- c. Group III, claim(s) 86, drawn to a method for the introduction of transduced cells into a tissue or organ, classified in class 435, subclass 325.
- d. Group IV, claim(s) 87, drawn to a method for the introduction of transduced cells into a blastocyst, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant situation each of the identified groups is directed toward a different method that accomplishes different scientific

objectives and employs disparate methodology steps and scientific reagents. For instance, Group I is simply directed toward a method of stably transducing hematopoietic stem cells by administering a vector and compound. However, Group II involves the administration of a transduced cell into a patient. Clearly these methodologies achieve different scientific objectives and employ different reagents/protocols.

Applicants are further advised that the following restriction requirement also applies to Group I: 1) applicants are required to identify and elect a single cell target (i.e., CD4⁺, CD8⁺, CD34⁺, dendritic cell, etc.); and 2) applicants are required to identify and elect a single cell surface binding molecule (i.e., polypeptide, lipid, nucleic acid, carbohydrate, ion, FLT-3 ligand, TPO ligand, KIT ligand; antibodies with the specificity of FLT-3L, TPOL, or KITL, CD3 ligand, CD28 ligand, CD25 ligand, CD71 ligand, CD69 ligand, antibodies with the specificity of CD3 ligand, CD28 ligand, CD25 ligand, CD71 ligand, or CD69 ligand, CD34, CD28, GM-CSF, IL-4, TNF-alpha, antibodies with the specificity of CD34, CD28, GM-CSF, IL-4, or TNF-alpha, etc.). Each cell surface binding molecule is structurally and functionally distinct and will necessitate independent searches for each molecule. Each of the identified target cell populations has unique genotypic/phenotypic characteristics that necessitate different transduction strategies and requires searches that are not coextensive in nature. Accordingly, each combination of cell surface binding molecule and cell target constitutes an independent and distinct invention.

Applicants are further advised that group I also contains numerous linking claims (i.e., claim 1 would link all of the aforementioned inventions). Upon the identification of a cell target and cell surface binding molecule, applicants should also

clearly identify those generic claims that read on the elected invention. See M.P.E.P. § 809.03. The restriction requirement of the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. § 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 U.S.P.Q. 129, 131-32 (C.C.P.A. 1971). See also M.P.E.P. § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). Applicant is also advised that the claims should be amended to reflect the election, where necessary.

37 C.F.R. § 1.48(b)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

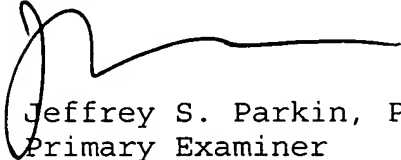
Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see

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<http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

27 November, 2005